The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database

Abstract

At the beginning of the artificial intelligence (AI)/machine learning (ML) era, the expectations are high, and experts foresee that AI/ML shows potential for diagnosing, managing and treating a wide variety of medical conditions. However, the obstacles for implementation of AI/ML in daily clinical practice are numerous, especially regarding the regulation of these technologies. Therefore, we provide an insight into the currently available AI/ML-based medical devices and algorithms that have been approved by the US Food & Drugs Administration (FDA). We aimed to raise awareness of the importance of regulatory bodies, clearly stating whether a medical device is AI/ML based or not. Cross-checking and validating all approvals, we identified 64 AI/ML based, FDA approved medical devices and algorithms. Out of those, only 29 (45%) mentioned any AI/ML-related expressions in the official FDA announcement. The majority (85.9%) was approved by the FDA with a 510(k) clearance, while 8 (12.5%) received de novo pathway clearance and one (1.6%) premarket approval (PMA) clearance. Most of these technologies, notably 30 (46.9%), 16 (25.0%), and 10 (15.6%) were developed for the fields of Radiology, Cardiology and Internal Medicine/General Practice respectively. We have launched the first comprehensive and open access database of strictly AI/ML-based medical technologies that have been approved by the FDA. The database will be constantly updated.